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APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-363

Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-363

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Joseph Lamendola, Ph.D.
Vice President, Regulatory Affairs

Dear Dr. Lamendola:

Please refer to your new drug application (NDA) dated April 9, 2001, received April 11, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex (desloratadine) Tablets.

We acknowledge receipt of your submissions dated April 19, May 22(2), and 25, June 1, August 7, and October 15, 2001, and January 16, 22, and 28 and February 4, and 6, 2002.

This new drug application provides for the use of Clarinex (desloratadine) Tablets for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients 12 years of age and older.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text, which includes minor revisions as discussed and agreed upon in a telephone conversations between Daniel McHugh of Schering Corporation and Anthony Zeccola of this division. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling including the minor revision.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-363." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27) for patients less then 12 years of age. We are deferring submission of your pediatric studies for this age group until December 7, 2002.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA. To comply with these regulations, all 3-day and 15-day alert reports, periodic adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-165 for this drug product, not to NDA 21-363. This includes the quarterly periodic adverse drug experience reports required by this new NDA. In the future, no submissions should be made to NDA 21-363 except for the 20 copies of the final printed labeling, as requested above.

If you have any questions, call Anthony M. Zeccola, Regulatory Management Officer, at 301-827-1058.

Sincerely,

/S/

{See appended electronic signature page}

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Meyer
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